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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,182

Applicant(s)

STAHLER ET AL.

Examiner

Dwayne K Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 13-30 is/are rejected.
- 7) ☒ Claim(s) 9, 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/1/02, 3/28/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

Claim Rejections - 35 USC § 101

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-30 provide for the use of a microfluidic reaction support, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 22-30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4, 6, 7, 14, 17-22, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al. (WO 96/15450). Zanzucchi teaches a microfluidic device for processing and analyzing multiple samples in wells. The device is comprised of a disc (14) having a flow channel structure that includes series of reaction areas (34, 36, 40, 42, 44) connected to feed channels (34, 50) and drain channel (46). The loading channel (50) feeds fluids in a vertical manner that is perpendicular to the flow channel structure. Loading channel (34) is a horizontal channel that flows parallel to flow channel structure. Figures 11A and 11B show other embodiments having vertical channels that provide feed and drain channels (315) that are perpendicular to the reaction areas. This embodiment also shows flow channel structures that are on both sides of the reaction support (instant claim 7). The use of glass for the disc (14) is taught on page 8, lines 1-11. A cover sheet of glass is disclosed at page 11, line 18. Figures 7C and 8 show a valve system that uses gating electrodes (162) for controlling fluid flow in the reactors and reservoirs. The valve system is described on page 16, lines 19-34. Zanzucchi teaches DNA binding and synthesis on page 11 and shows array synthesis on page 17.

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4. Claims 1-7, 13-15, 17-22 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfof (6,485,690). Pfof teaches a multilayered fluidic array having microchannels, reservoirs and reaction wells. The device is best shown in Figures 1, 2 and 6-8. This embodiment is described at column 5, line 50 – column 6, line 46. The device is comprised of several layers (12, 14 and 16) having flow channels that run parallel (26) to the layers as well as flow channels that are perpendicular (20, 22, 32, 34) to the layers. Flow channel 20 is a feed channel, while channel 34 serves as a drain. The bottom layer of the device contains reaction wells (30). Pfof discloses materials of construction including glass and silicon in column 6, lines 33-40. DNA synthesis and receptor binding is taught in column 5, lines 1-48.

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al. (6,485,690) in view of Craighead (5,867,266). Pfof teaches every element of claim 8 except for microlens structures integrated specifically into the cover layer. Pfof does state that microlenses may be integrated any layer of their device (column 11, lines 40-55). Craighead teaches an optical analysis device having multiple channels (12, 14, 16, 18) for containing DNA samples to be analyzed. The channels are aligned with microlenses (32, 34, 36, 38) that focus laser beams to the channels such that labeled DNA fragments will fluoresce at a known wavelength (column 5, lines 1-29). It would have been obvious to one of ordinary skill in the art to add the microlenses from

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Craighead to the cover layer of Pfof. One would add the microlenses to the cover layer in order to focus and direct light in the device.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (WO 96/15450) in view of Parce et al. (WO 98/02728). Zanzucchi teaches every element of claim 10 except for making walls lightproof. Parce teaches a microfluidic system for electrophoretic analysis of materials. The device is comprised of substrates having microchannels. An embodiment of the device disclosed on page 14 (line 34) includes a mask imposed on the substrate to provide darkened regions that shield areas of the channels from light during optical analysis. It would have been obvious to one of ordinary skill in the art to combine the mask element from Parce with the device of Zanzucchi. One would add the mask to selectively darken elements of the device and prevent interference from reflected light.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al. (6,485,690) in view of Stabile et al. (5,872,623). Pfof teaches every element of claim 16 except for a CCD integrated into cover layer. Pfof does state that optical or detection elements may be integrated any layer of their device (column 11, lines 40-55). Stabile teaches an apparatus for detecting light from closely spaced detection sites. The embodiment most relevant to the instant claims is shown in Figure 6 and described in column 11, lines 30-46. In Figure 6, Stabile shows 3 layers with the lower layer having a CCD. It would have been obvious to one of ordinary skill in the art to add the CCD

layer from Stabile to the device of Pfof. One would add the CCD to detect light emitted from the analyzed material in the wells.

Allowable Subject Matter

10. Claims 9, 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Walt et al. (6,210,910) shows an optical analysis device comprised of bundled etched glass fibers. Hollis et al. (5,846,708) teaches an analysis device having a CCD integrated onto a substrate. Southgate et al. (5,863,502) teaches a multilayer parallel reaction device.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
March 20, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700